August 3, 2000

MEMORANDUM

SUBJECT: **DICLOFOP-METHYL.** Revised Anticipated Residue Estimates and Dietary Risk Assessment.

Chemical No.	110902
Reregistration Case:	2160
DP Barcode:	D267649

FROM: Richard Griffin
Reregistration Branch II
Health Effects Division

THROUGH: Chemistry Science Advisory Council
Dietary Exposure Science Advisory Committee
Health Effects Division

and

Alan Nielsen, Branch Senior Scientist
Reregistration Branch II
Health Effects Division

TO: Christina Jarvis
Reregistration Branch II
Health Effects Division (7509C)

The May 30, 2000 dietary risk assessment (R. Griffin memo to C. Jarvis) has been revised based on comments made by the registrant (Aventis CropScience USA LP, 6/30/2000) and on further analysis of current use practices of diclofop-methyl on wheat forage for dairy cattle.

This memo summarizes the toxicological endpoints and dose levels selected for dietary risk assessment and summarizes the usage and residue data on which exposure estimates are based. All available data, including USDA/PDP and FDA surveillance data have been considered to estimate exposure. Dietary risk assessment considering

both acute and chronic exposure is based on anticipated residue estimates for barley grain, wheat grain, and associated livestock commodities (dairy and beef products).

Summary

Dietary risk assessment for diclofop-methyl is based on its use on the two agricultural applications supported by the registrant for reregistration, wheat and barley. Metabolism and feeding studies, which demonstrated a “transfer” of residues to animal tissues and milk, have necessitated additional tolerances and the risk assessment of possible exposure *via* milk, milk products, and ruminant meats.

Toxicological endpoints for risk assessment are developmental toxicity (acute exposure) and liver toxicity (chronic exposure). Diclofop-methyl is characterized as a “likely human carcinogen” with quantification of risk based on a linear low-dose approach using an upper-bound potency factor (Q_1*) and an estimate of average (lifetime) dietary exposure.

Dietary exposure estimates are based on field trial data, processing data, feeding studies, and Agency estimates of percent usage on barley (<1%) and wheat (<2%). Estimates are also based on an analysis of diclofop-methyl use patterns and the use of wheat forage in dairy production. Although the USDA/PDP and the FDA have sampled wheat grain, barley grain, and milk products for diclofop-methyl, monitoring data have not been used for this risk assessment due primarily to uncertainty concerning the detection of diclofop-methyl metabolites.

Estimated dietary exposure to diclofop-methyl is less than 8% of the acute Population Adjusted Dose (aPAD) at the 99.9th exposure level for females of child-bearing age, and less than 1% of the chronic Population Adjusted Dose (cPAD) for the general U.S. population or any population sub-groups. The estimated *upper-bound* carcinogenic risk for the general U.S. population is 1.2×10^{-6}.

Toxicological Information / Endpoint Selection for Dietary Risk Assessment

Non-Carcinogenic Endpoints for Risk Assessment

The HED Hazard Identification Assessment Review Committee (HIARC) established the following doses for dietary risk assessment based on non-carcinogenic effects (DICLOFOP-METHYL - Revised Report of the Hazard Identification Assessment Review Committee, R. Fricke, 3/2/2000 and 8/2/2000):

Acute Population Adjusted Dose (aPAD): Estimates of acute dietary exposure are compared to a dose of 0.1 mg/kg body weight/day. The aPAD dose is based on a NOAEL of 10 mg/kg/day and uncertainty factors of 10x for interspecies extrapolation and 10x for intraspecies variability with no additional factor for FQPA considerations

(DICLOFOP-METHYL - Report of the FQPA Safety Factor Committee, B. Tarplee, 4/24/2000). The endpoint is developmental toxicity, established in a developmental toxicity study in the rat which demonstrated adverse developmental effects attributable to a single dose. Developmental risk is based on the estimated acute dietary exposure of U.S. females within the child-bearing age range of 13 to 50 years. Based on the toxicological data for diclofop-methyl, the HIARC also concluded that acute dietary risk assessment is not appropriate for the general U.S. population or other population sub-groups since an acute endpoint, other than developmental toxicity, was not identified.

Chronic Population Adjusted Dose (cPAD): Estimates of chronic dietary exposure are compared to a dose of 0.0023 mg/kg body weight/day. The cPAD dose is based on a NOAEL of 0.23 mg/kg body weight/day and uncertainty factors of 10x for interspecies extrapolation and 10x for intraspecies variability with no additional factor for FQPA considerations. (DICLOFOP-METHYL - Report of the FQPA Safety Factor Committee, B. Tarplee, 4/24/2000). The endpoint is liver toxicity, established in a combined chronic feeding and carcinogenicity study in the rat. Chronic dietary risk estimates are calculated for the general U.S. population and all U.S. population sub-groups including infants and children.

Carcinogenic Risk Assessment

The HED Cancer Assessment Review Committee (CARC) met on March 22, 2000 and concluded that diclofop-methyl should be classified as a “likely human carcinogen”. The Committee also recommended a linear low-dose (Q_1*) approach for human risk characterization, based on hepatocellular tumors observed in a carcinogenicity study in the mouse. Quantified carcinogenic risk estimates are based on an *upper-bound* potency factor (Q_1*) of 2.3 x10^{-1} (mg/kg/day)$^{-1}$ and are calculated based on the chronic (averaged) exposure estimate for the general U.S. population.

Endpoint selection and doses for risk assessment are summarized in Table 1 below:

Table 1. Endpoint / Dose Summary

EXPOSURE SCENARIO	DOSE (mg/kg/day)	ENDPOINT	STUDY
Acute Dietary (Females 13 - 50)	NOAEL = 10 mg/kg/day	Decreased fetal body wts, distended ureters, skeletal abnormalities. These effects could be attributed to a single dose.	870.3700 Developmental toxicity study in the rat (92036042)
	UF = 100	Acute PAD = 0.1 mg/kg/day	
Acute Dietary (General Population including Infants and Children)	None	No endpoint selected	None
Chronic Dietary (Non-cancer)	NOAEL = 0.23 mg/kg/day	Based on increased relative liver and kidney wts, liver enzymes, liver histopathology (hypertrophy, lipofuscin storage). Effects and NOAEL consistent with other studies in mouse and dog.	870.4300 Chronic toxicity study in the rat (43927302)
	UF = 100	Chronic PAD = 0.0023 mg/kg/day	
Cancer	Q_1* of 2.3×10^{-1} $(mg/kg/day)^{-1}$	Based on liver adenomas and carcinomas with significant trend and pair-wise comparisons.	870.4200 Mouse Carcinogenicity Study (92036058)

Residue Information

CFR

Tolerances for residues of diclofop-methyl are established under 40 CFR 180.385(a) for barley grain/straw and wheat grain/straw. Additional tolerances are needed under 40 CFR 180.385(a)(1) for barley hay and wheat hay/forage. Additional tolerances are also needed under 40 CFR 180.385(a)(2) for milk and livestock commodities (except poultry commodities).

Residues of Concern

On April 4, 2000 the HED Metabolism Assessment Review Committee determined the residue of concern for plant commodities is diclofop-methyl and its metabolites diclofop acid and hydroxy diclofop (free and conjugated). The residue of concern for animal commodities is diclofop-methyl and diclofop acid (free and conjugated).

A conclusion was also made that, for the purposes of risk assessment, diclofop-methyl (parent) and its metabolites are to be considered toxicologically equivalent (Diclofop-methyl. Outcome of HED Metabolism Assessment Review Committee *ad hoc* Meeting on 4/4/2000, S. Piper, 4/7/2000).

Preliminary Risk Assessment / Need for Refinement

Dietary exposure estimates for diclofop-methyl, if based on reassessed tolerances (see Product and Residue Chemistry Chapters for the Reregistration Eligibility Decision Document, S. Piper, 5/2/2000) and an assumption of 100% treatment of barley and wheat, exceed the levels of "concern" established by HED for each risk parameter (cPAD, aPAD, carcinogenic risk). This upper-bound, or screening, type of assessment can be described as a "Tier 1" risk assessment. Milk, with a proposed tolerance of 4 ppm, is the most significant contributor to dietary exposure estimates and is of particular concern in regard to childhood exposure. A refinement to the dietary risk assessment has been made by using estimates of actual usage on wheat and barley (percent crop treated data), and by using estimates of residues expected at the time of consumption, or "anticipated" residues.

Usage Data

Annual usage of diclofop-methyl on barley and wheat has been estimated by the Biological and Economic Analysis Division (BEAD) based on EPA, USDA/NASS, NCFAP, and other data sources (Quantitative Usage Analysis for Diclofop-Methyl, A. Halvorson, 2/17/99). Use estimates were revised by BEAD on 7/14/2000 (personal communication, V. Dietrich to R. Griffin). Diclofop-methyl is estimated to be currently used on less than 1 percent (0.5%) of the total U.S. barley crop. Diclofop-methyl usage on wheat varies somewhat according to variety, with an estimated use of 1.2% on winter wheat (approximately 50% of total wheat production), 0.4% use on spring wheat, and an estimated 12% use on durum wheat (< 4% total wheat production). Total usage on wheat is estimated to be less than 2% of all wheat grown in the U.S.

It should be noted that >90% of diclofop-methyl usage is a post-emergence use which in turn leads to considerations for livestock exposure *via* foraging of treated wheat (Diclofop Usage on Wheat by Application Timing, A. Halvorson 4/21/2000). However, chronic risk assessment for diclofop-methyl in milk is based in part on expert opinion that, at most, 15% of dairy cattle *may* consume wheat forage (personal communication D. Putnam to V. Dietrich, 7/17/2000). Data indicate barley is not a significant forage item.

The registrant has reported, and Agency data confirm that there has been an overall decline of diclofop-methyl usage due to the introduction of other herbicides.

Anticipated Residue Data Sources

The residue estimates for diclofop-methyl and/or its metabolites that may occur in barley grain, wheat grain, milk or animal tissues have been refined to reflect the time intervals and processes which reduce pesticide residues between use and the time of consumption. The Agency calls the refined residue estimates "anticipated residues" to distinguish these residue estimates from those that support tolerances. The following describes the data sources for diclofop-methyl anticipated residues.

Submitted Data: Dietary risk assessment for diclofop-methyl is based, in part, on "magnitude of the residue" data (field trial data) and processing studies submitted by the registrant in support of the reregistration for wheat and barley grain, hay, and forage. Dietary risk assessment for diclofop-methyl is also based on submitted ruminant and poultry feeding studies that established the level of diclofop-methyl residue "transfer" to animal tissue, milk, and eggs.

Monitoring Data/PDP: The USDA Pesticide Data Program (PDP) sampled wheat grain for diclofop-methyl in 1995 (600 samples), 1996 (340 samples), and 1997 (623 samples). Of these samples, there are two detections reported at 0.009 ppm and 0.01 ppm. The Limit of Detection (LOD) is listed at 0.006 ppm for all samples/years. Soybean grain was also monitored by the PDP in 1997 and 1998, with no detections of diclofop-methyl.

Monitoring Data/FDA: FDA domestic surveillance data (years 1992-1998) is also available for diclofop-methyl residue in whole grain barley, whole grain wheat, processed wheat commodities, whole milk, and milk products including cream and cheese. There are no reported detections of diclofop-methyl in any samples. Data indicate the Limit of Quantitation (LOQ) for FDA milk samples does not exceed 0.01 ppm. There is no FDA surveillance data for diclofop-methyl residue in animal tissue.

Residue Estimates for Acute Risk Assessment

Wheat/Barley Grain: The combined residues of diclofop-methyl and its metabolites, diclofop acid and hydroxy diclofop were nondetectable (< 0.10 ppm) in field trial studies in/on wheat and barley grain. Wheat and barley processing data demonstrate that residues of diclofop-methyl and its metabolites, diclofop acid and hydroxy diclofop do not concentrate in bran, flour, or other processed fractions following postemergence foliar application at 5x the label rate.

Since wheat and barley grain are blended and processed prior to consumption, the residue estimate for risk assessment is based on ½ the LOQ (0.05 ppm in field trial studies), a (reduction) factor of 0.2 based on field trial data at 5x label rate, and finally factored for the (rounded up) percent of total crop treated (1% for barley and 2% for wheat). On this basis, the residue estimates for acute risk assessment are 0.0001 ppm

for barley grain and 0.0002 ppm for wheat grain.

Since barley and wheat grain are highly blended commodities, the extrapolated values were selected for risk assessment, with the monitoring data serving as confirmation of the estimates used.

Animal Tissues: Metabolism studies have demonstrated a “transfer” of diclofop-methyl and diclofop acid to animal tissue (meats/fat/internal organs). Lacking monitoring data for these commodities, this aspect of the acute dietary risk assessment relies on extrapolated residue levels based on an estimate of the possible exposure, or “burden”, to livestock from treated items, and transfer factors derived from ruminant and poultry feeding studies.

Data from the poultry feeding study and an estimate of a low dietary residue burden for poultry led to a decision that a tolerance is not required for eggs or other poultry commodities. On the same basis, poultry products have not been included in this dietary risk assessment.

A dietary burden reflecting a theoretical maximum exposure to diclofop-methyl for beef cattle (extrapolated to goats and sheep) and swine, is based on the feed items of wheat grain, wheat forage, and barley hay (for acute assessment assumes 100% treatment of each item). Residue estimates for wheat forage (the most significant contribution to the diclofop-methyl dietary burden) are based on field trial measurements at day 26 following postemergence treatment. Although residue measurements for forage at day 10 following application were used to establish tolerances, the 26 day interval from application to foraging is considered a better estimate of actual agricultural practices and more suitable for risk assessment. From these data a dietary burden of 1.86 ppm was established for beef cattle and for swine (based on wheat grain *only*) a dietary burden of 0.045 ppm was established.

Ruminant feeding study data were used to derive estimates of residue transfer from plant feed items to liver, kidney, fat, and muscle of beef cattle, and swine (see Table 4, Poultry and Ruminant Feeding Studies for Diclofop-Methyl, S. Piper, 2/29/2000). Since the assessment is for an acute, or maximum, exposure the highest measured residue from the feeding study dose level most closely corresponding to the estimated dietary burden of 1.86 ppm was used to calculate the final transfer factor for each of the above tissues.

Based on the data outlined above (residue burden x transfer factor), the ruminant tissue residue estimates for acute dietary risk are: 0.046 ppm in meat and meat byproducts, 0.13 ppm in fat, 0.84 ppm in kidney, and 0.22 ppm in liver.

Swine tissue residue estimates, which are based on wheat grain only, are assessed at:

0.001 ppm in meat/byproducts, 0.003 ppm in fat, 0.02 ppm in kidney, and 0.0054 ppm in liver.

Milk: Although extensive FDA surveillance monitoring data is listed for diclofop-methyl in milk and milk products (with no reported detections of diclofop-methyl), a decision was made to not use FDA data for risk assessment. This decision was made because it could not be determined if the FDA method identified the metabolite expected in milk.

The dietary burden for dairy cattle was estimated as above, except averaged residues from field trial studies were used instead of maximum residues to account for the blending that occurs in milk processing. Transfer factors were based on averaged residues from the feeding study dose level most closely corresponding to the estimated dietary burden of 2.12 ppm.

Based on the data outlined above (residue burden x transfer factor), the residue estimates for acute dietary risk from dairy products is 0.22 ppm in whole milk (0.22 ppm is entered for each milk category in the DEEM program; nonfat solids, fat solids, sugar, and water).

Dietary Burden Estimates are summarized below:

Table 2. Dietary Burden Estimates

Feed Commodity	% Dry Matter [a]	% Diet	Residues (ppm)[c]	Dietary Contribution (ppm)[b]
Beef Cattle				
Wheat forage	25	25	1.77[d]	1.77
Barley hay	88	25	0.22[d]	0.062
Wheat grain	89	50	0.05	0.028
TOTAL BURDEN		100		1.86
Dairy Cattle				
Wheat forage	25	42	1.24[e]	2.08
Barley hay	88	28	0.16[e]	0.052
Wheat grain	89	30	0.05	0.01
TOTAL BURDEN		100		2.15
Swine				
Wheat grain	89	80	0.05	0.045
TOTAL BURDEN		80		0.045

a= OPPTS Guideline 860.1000
b= Contribution = [residue / % DM (if cattle)] x % diet].
c= Anticipated residue
d= HAFT at 26-day PHI from field trials.
e= average residues from field trials.

Residue Estimates for Chronic Risk Assessment

Wheat/Barley Grain: The combined residues of diclofop-methyl and its metabolites, diclofop acid and hydroxy diclofop were nondetectable (<0.10 ppm) in/on wheat and barley grain in field trial studies. Wheat and barley processing data demonstrate that residues of diclofop-methyl and its metabolites, diclofop acid and hydroxy diclofop do not concentrate in bran, flour, etc. following postemergence foliar application at 5x the label rate. Since wheat and barley grain are blended commodities, the residue estimate for risk assessment is based on ½ the LOD (0.05 ppm in field trial studies), a reduction factor of 0.2 based on field trial data at 5x label rate, and factored for the percent of total crop treated (2% for wheat and 0.5% for barley). On this basis, the residue estimates for chronic risk assessment are 0.00005 ppm for barley grain (and processed commodities) and 0.0002 ppm for wheat grain (and processed

commodities).

Animal Tissues: Residue estimates for the assessment of chronic risk due to diclofop-methyl residue in ruminant meats (and pork) were derived from the residue estimates summarized above for acute risk assessment. However, each acute residue estimate has been factored for percent crop treated data, with the intent to more accurately reflect the variations of exposure expected over the long-term (cancer risk is based on an assumed lifetime exposure).

Based on the data outlined above (residue burden x transfer factor x percent crop treated) the residue estimates for chronic dietary risk from residues in ruminant tissues are: 0.0009 ppm in meat/meat byproducts, 0.0025 ppm in fat, 0.017 ppm in kidney, and 0.004 in liver.

Swine tissues are estimated at: 0.00002 ppm in meat/meat byproducts, 0.00004 ppm in fat, 0.0004 ppm in kidney, and 0.00009 in liver.

Milk: Residue estimates for the assessment of chronic risk due to diclofop-methyl residue in milk (and milk products) were derived from the residue estimates summarized above for acute risk assessment. However, estimates for chronic risk assessment were factored for percent crop treated (1.6% for wheat forage) and for the estimated percent of total dairy cattle that *may* forage spring or winter wheat. The estimate for dairy cattle foraging, believed to be an upper-bound estimate, is 15% of total.

Based on the data outlined above (average residue burden x average transfer factor x percent crop treated x percent forage), the residue estimate for chronic dietary risk from milk and milk products is: 0.0005 ppm (0.0005 is entered for each milk category in the DEEM program; nonfat solids, fat solids, sugar, and water).

Food Consumption Estimates / DEEM™ Software

The Agency is currently using software named the *Dietary Exposure Evaluation Model*, or DEEM™, to calculate acute and chronic dietary risk estimates for the general U.S. population and defined population subgroups, including infants and children. Food consumption data used in the program is based on the *USDA Continuing Survey of Food Intake by Individuals* (CSFII). The Agency is currently using the CSFII 1989-92 consumption data, which is based on the reported food consumption of 10,383 individuals over a 3 day interval. Foods “as eaten” (such as cherry pie) are linked to Raw Agricultural Commodities (RACs) such as cherries, wheat, oil, etc. by the use of “recipe” translation files.

Acute dietary exposure estimates are *not* based on averaged consumption data.

Instead, the program references each individual record of consumption and produces a distribution (from the10th to the 99.9th exposure percentile) of daily exposures for individuals comprising the U.S. population and/or population subgroups (for this assessment, females 13-50 years of age). Acute dietary exposure estimates are calculated by the DEEM™ program in mg/kg body weight/day and risk is calculated as a percent of the aPAD.

Chronic dietary exposure estimates are based on averaged consumption data for the entire U.S. population, and within population subgroups such as “all infants”. For this assessment, the averaged consumption estimate of each population group is multiplied by residue estimates outlined above for wheat/barley grain, livestock tissue, and milk. Chronic dietary exposure estimates are calculated by the DEEM™ program in mg/kg body weight/day and dietary risk is calculated as a percent of the cPAD.

Dietary Risk Estimates

Acute Dietary Risk

The DEEM™ model was used to calculate acute dietary exposure estimates based on total single-day consumption data. Based on the residue and consumption data outlined above, the DEEM™ program estimates that the population sub-group of U.S. females (age 13-50) are acutely exposed to diclofop-methyl at a level that is less than 8% (at the 99.9% exposure percentile) of the respective aPAD. (DEEM acute summary attached).

Chronic Dietary Risk

The DEEM™ model was used to calculate chronic dietary exposure estimates based on average consumption data for the U.S. population and U.S. population subgroups including infants and children. Based on the residue and percent crop treated data outlined above, the DEEM™ model estimates that the U.S. population and all population subgroups, including infants and children, are chronically exposed to diclofop-methyl at a level less than 1% of the respective cPAD. (DEEM chronic summary attached).

Population	Chronic Dietary		Acute Dietary (99.9th percentile)	
	Exposure (mg/kg/d)	% cPAD	Exposure (mg/kg/d)	% aPAD
U.S. General Population	0.000005	<1%	n/a	n/a
Children (1-6 years)	0.000016	<1%	n/a	n/a
All infants (< 1 year)	0.000007	<1%	n/a	n/a
Females (13-50 years)	0.000003	<1%	0.007558	<8%

Carcinogenic Risk

Carcinogenic risk for diclofop-methyl is quantified, based on the estimated average dietary exposure of the general U.S. population (0.000005 mg/kg bw/day) multiplied by the upper-bound potency factor (Q_1*) of 2.3 x10^{-1} (mg/kg/day)$^{-1}$. On this basis, the *upper-bound* carcinogenic risk estimate for diclofop-methyl is calculated to be 1.2 x 10^{-6}, which is the level (10^{-6}) generally considered negligible by the Agency.

cc: RF, Reg. Std. File, R. Griffin, L. Richardson
CM2: Rm 712B: 703.305.5715

SUMMARY - Residue estimates for acute risk assessment

U.S. Environmental Protection Agency Ver. 7.075
DEEM Acute analysis for DICLOFOP-METHYL
Residue file name: D:\110902ac.rs7
Analysis Date 07-26-2000 Residue file dated: 07-26-2000/16:07:47/8
Reference dose: aRfD = 0.1 mg/kg bw/day NOEL = 10 mg/kg bw/day

Food Code	Crop Grp	Food Name	Def Res (ppm)	Adj.Factors #1	#2
265	15	Barley	0.000100	1.000	1.000
276	15	Wheat-rough	0.000200	1.000	1.000
277	15	Wheat-germ	0.000200	1.000	1.000
278	15	Wheat-bran	0.000200	1.000	1.000
279	15	Wheat-flour	0.000200	1.000	1.000
318	D	Milk-nonfat solids	0.220000	1.000	1.000
319	D	Milk-fat solids	0.220000	1.000	1.000
320	D	Milk sugar (lactose)	0.220000	1.000	1.000
321	M	Beef-meat byproducts	0.046000	1.000	1.000
322	M	Beef-other organ meats	0.220000	1.000	1.000
323	M	Beef-dried	0.092000	1.000	1.000
324	M	Beef-fat w/o bones	0.130000	1.000	1.000
325	M	Beef-kidney	0.840000	1.000	1.000
326	M	Beef-liver	0.220000	1.000	1.000
327	M	Beef-lean (fat/free) w/o bones	0.046000	1.000	1.000
328	M	Goat-meat byproducts	0.046000	1.000	1.000
329	M	Goat-other organ meats	0.220000	1.000	1.000
330	M	Goat-fat w/o bone	0.130000	1.000	1.000
331	M	Goat-kidney	0.840000	1.000	1.000
332	M	Goat-liver	0.220000	1.000	1.000
333	M	Goat-lean (fat/free) w/o bone	0.046000	1.000	1.000
336	M	Sheep-meat byproducts	0.046000	1.000	1.000
337	M	Sheep-other organ meats	0.220000	1.000	1.000
338	M	Sheep-fat w/o bone	0.130000	1.000	1.000
339	M	Sheep-kidney	0.840000	1.000	1.000
340	M	Sheep-liver	0.220000	1.000	1.000
341	M	Sheep-lean (fat free) w/o bone	0.046000	1.000	1.000
342	M	Pork-meat byproducts	0.001000	1.000	1.000
343	M	Pork-other organ meats	0.005400	1.000	1.000
344	M	Pork-fat w/o bone	0.003000	1.000	1.000
345	M	Pork-kidney	0.020000	1.000	1.000
346	M	Pork-liver	0.005400	1.000	1.000
347	M	Pork-lean (fat free) w/o bone	0.001000	1.000	1.000
398	D	Milk-based water	0.220000	1.000	1.000
437	15	Wheat-germ oil	0.000200	1.000	1.000

SUMMARY - Acute risk estimates for 95th, 99th, and 99.9th exposure percentiles

U.S. Environmental Protection Agency Ver. 7.075
DEEM ACUTE analysis for DICLOFOP-METHYL (1989-92 data)
Residue file: 110902ac.rs7 Adjustment factor #2 NOT used.
Analysis Date: 07-26-2000/16:09:02 Residue file dated: 07-26-2000/16:07:47/8
NOEL (Acute) = 10.000000 mg/kg body-wt/day
Daily totals for food and foodform consumption used.
Run Comment: ""

Summary calculations (per capita):

95th Percentile			99th Percentile			99.9th Percentile		
Exposure	% aRfD	MOE	Exposure	% aRfD	MOE	Exposure	% aRfD	MOE
Females 13-50 yrs:								
0.002851	2.85	3507	0.004399	4.40	2273	0.007558	7.56	1323

SUMMARY - Residue estimates for chronic risk assessment

U.S. Environmental Protection Agency Ver. 7.075
DEEM Chronic analysis for DICLOFOP-METHYL 1989-92 data
Residue file: D:\110902cr.rs7 Adjust. #2 NOT used
Analysis Date 07-26-2000 Residue file dated: 07-21-2000/16:00:41/8
Reference dose (RfD) = 0.0023 mg/kg bw/day

Food Code	Crop Grp	Food Name	RESIDUE (ppm)	Adj.Factors #1	#2
265	15	Barley	0.000050	1.000	1.000
276	15	Wheat-rough	0.000200	1.000	1.000
277	15	Wheat-germ	0.000200	1.000	1.000
278	15	Wheat-bran	0.000200	1.000	1.000
279	15	Wheat-flour	0.000200	1.000	1.000
318	D	Milk-nonfat solids	0.000500	1.000	1.000
319	D	Milk-fat solids	0.000500	1.000	1.000
320	D	Milk sugar (lactose)	0.000500	1.000	1.000
321	M	Beef-meat byproducts	0.000900	1.000	1.000
322	M	Beef-other organ meats	0.004000	1.000	1.000
323	M	Beef-dried	0.001800	1.000	1.000
324	M	Beef-fat w/o bones	0.002500	1.000	1.000
325	M	Beef-kidney	0.017000	1.000	1.000
326	M	Beef-liver	0.004000	1.000	1.000
327	M	Beef-lean (fat/free) w/o bones	0.000900	1.000	1.000
328	M	Goat-meat byproducts	0.000900	1.000	1.000
329	M	Goat-other organ meats	0.004000	1.000	1.000
330	M	Goat-fat w/o bone	0.002500	1.000	1.000
331	M	Goat-kidney	0.017000	1.000	1.000
332	M	Goat-liver	0.004000	1.000	1.000
333	M	Goat-lean (fat/free) w/o bone	0.000900	1.000	1.000
336	M	Sheep-meat byproducts	0.000900	1.000	1.000
337	M	Sheep-other organ meats	0.004000	1.000	1.000
338	M	Sheep-fat w/o bone	0.002500	1.000	1.000
339	M	Sheep-kidney	0.017000	1.000	1.000
340	M	Sheep-liver	0.004000	1.000	1.000
341	M	Sheep-lean (fat free) w/o bone	0.000900	1.000	1.000
342	M	Pork-meat byproducts	0.000020	1.000	1.000
343	M	Pork-other organ meats	0.000090	1.000	1.000
344	M	Pork-fat w/o bone	0.000040	1.000	1.000
345	M	Pork-kidney	0.000400	1.000	1.000
346	M	Pork-liver	0.000090	1.000	1.000
347	M	Pork-lean (fat free) w/o bone	0.000020	1.000	1.000
398	D	Milk-based water	0.000500	1.000	1.000
437	15	Wheat-germ oil	0.000200	1.000	1.000

SUMMARY - Chronic risk estimates

U.S. Environmental Protection Agency Ver. 7.075
DEEM Chronic analysis for DICLOFOP-METHYL (1989-92 data)
Residue file name: D:\110902cr.rs7 Adjustment factor #2 NOT used.
Analysis Date 07-26-2000/13:34:19 Residue file dated: 07-21-2000/16:00:41/8
Reference dose (RfD, Chronic) = .0023 mg/kg bw/day

Total exposure by population subgroup

Population Subgroup	Total Exposure mg/kg body wt/day	Total Exposure Percent of Rfd
U.S. Population (total)	0.000005	0.2%
U.S. Population (spring season)	0.000005	0.2%
U.S. Population (summer season)	0.000005	0.2%
U.S. Population (autumn season)	0.000005	0.2%
U.S. Population (winter season)	0.000005	0.2%
Northeast region	0.000005	0.2%
Midwest region	0.000006	0.2%
Southern region	0.000005	0.2%
Western region	0.000005	0.2%
Hispanics	0.000006	0.2%
Non-hispanic whites	0.000005	0.2%
Non-hispanic blacks	0.000005	0.2%
Non-hisp/non-white/non-black	0.000005	0.2%
All infants (< 1 year)	0.000007	0.3%
Nursing infants	0.000002	0.1%
Non-nursing infants	0.000009	0.4%
Children 1-6 yrs	0.000016	0.7%
Children 7-12 yrs	0.000009	0.4%
Females 13-19 (not preg or nursing)	0.000004	0.2%
Females 20+ (not preg or nursing)	0.000003	0.1%
Females 13-50 yrs	0.000003	0.1%
Females 13+ (preg/not nursing)	0.000005	0.2%
Females 13+ (nursing)	0.000004	0.2%
Males 13-19 yrs	0.000006	0.2%
Males 20+ yrs	0.000003	0.1%
Seniors 55+	0.000003	0.1%
Pacific Region	0.000005	0.2%